

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK**

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| State Farm Mutual Automobile Insurance Company, |) | |
| |) | |
| Plaintiff, |) | Case No. |
| |) | |
| v. |) | PLAINTIFF DEMANDS |
| |) | TRIAL BY JURY |
| 21st Century Pharmacy, Inc., |) | |
| Albert Alishayev, |) | |
| Timothy Morley, D.O., |) | |
| Azu A. Ajudua, M.D., |) | |
| Vincentiu Popa, M.D., and |) | |
| Jo-Ann Shakarjian, M.D. |) | |
| |) | |
| Defendants. |) | |

COMPLAINT

State Farm Mutual Automobile Insurance Company (“State Farm Mutual”), for its complaint against 21st Century Pharmacy, Inc., Albert Alishayev, Timothy Morley, D.O., Azu Ajudua, M.D., Vincentiu Popa, M.D., and Jo-Ann Shakarjian, M.D., alleges as follows:

I. NATURE OF THE ACTION

1. This action seeks to recover money fraudulently and unjustly obtained from State Farm Mutual through the submission of bills and supporting documentation for topical compounded medications (“Compounded Products”) provided to individuals (“State Farm Mutual Insureds”) who were involved in automobile accidents and eligible for benefits under State Farm Mutual insurance policies.

2. The Compounded Products were provided to State Farm Mutual Insureds by 21st Century Pharmacy, Inc. (“21st Century”) and purportedly prescribed for pain relief by Timothy Morley, D.O. (“Morley”), Azu Ajudua, M.D. (“Ajudua”), Vincentiu Popa, M.D. (“Popa”), and

Jo-Ann Shakarjian, M.D. (“Shakarjian”), and other physicians (collectively the “Prescribing Doctors”) in New York.

3. The scheme involves 21st Century’s preparation of Compounded Products, which consist of various drugs combined in a topical cream, and the prescription of those Compounded Products by the Prescribing Doctors, to treat patients who have been in automobile accidents and who allegedly complain of musculoskeletal pain or neuropathies.

4. Compounded Products are appropriate when the unique needs of an individual patient cannot be met by a Federal Drug Administration (“FDA”) approved medication. 21st Century’s topical Compounded Products, however, are not tailored to the particular needs of any one patient. Rather, 21st Century simply assembles a routine combination of ingredients in a cream form, provides these creams to a variety of patients and charges as much as almost \$9,000 for a 300 gram (or about 10 ounces) tube. *See* Ex. 1.

5. 21st Century knows these Compounded Products include individual ingredients that are not medically necessary because they do not have a therapeutic effect on the conditions for which they are prescribed, knows that the combination of multiple ingredients does not achieve any beneficial effect and results in exorbitant charges, and knows there is no reason to provide Compounded Products for which there is either no support or very limited support when there are a wide range of commercially available, FDA approved medications, that are proven to have therapeutic effects for the same conditions, available at a fraction of the cost.

6. 21st Century’s charges are supported by prescriptions and letters of medical necessity from the Prescribing Doctors. The prescriptions and letters of medical necessity are largely form documents, many of which are supplied by 21st Century to the Prescribing Doctors, to be completed and signed. The prescriptions consist of predetermined lists of Compounded

Products manufactured by 21st Century on which the Prescribing Doctors circle or mark the one they are prescribing for their patient. The letters of medical necessity contain boilerplate language that attest to the purported necessity of the Compounded Products. 21st Century submits charges for these Compounded Products to State Farm Mutual knowing that it is not entitled to be paid for the Compounded Products because they are not medically necessary.

7. 21st Century and the Prescribing Doctors know the Compounded Products are not medically necessary or efficacious for the conditions for which they are prescribed because, among other things: (a) the Compounded Products include drugs without documented therapeutic effect from topical application for the conditions for which they are prescribed; (b) there is no legitimate basis for combining the drugs 21st Century uses into its Compounded Products; (c) there is no legitimate reason to provide patients with expensive Compounded Products (as much as almost \$9,000 per 10 ounce tube) and which include drugs and combinations of drugs whose efficacy in topical form is undocumented and unsupported when there are many other widely accepted alternatives with well-documented therapeutic benefits that are commercially available at considerably lower cost; and (d) the Compounded Products were not approved by the FDA and were not exempted from requiring FDA approval because they were not prepared for the unique needs of any identified individual patient.

8. 21st Century and the Prescribing Doctors' scheme began at least as early as 2014 and has continued uninterrupted since that time. As a result of 21st Century and the Prescribing Doctors' scheme, State Farm Mutual has incurred damages of more than \$1.6 million.

II. JURISDICTION AND VENUE

9. Pursuant to 28 U.S.C. § 1332(a)(1), this Court has jurisdiction over all claims because the matter in controversy exceeds the sum or value of \$75,000, exclusive of interest and costs, and is between citizens of different states.

10. Pursuant to 28 U.S.C. § 1391(b), venue is proper in this district because a substantial part of the events or omissions giving rise to the claims occurred here.

III. PARTIES

A. Plaintiff

11. State Farm Mutual is a corporation organized under the laws of Illinois, with its principal place of business in Illinois, and issues automobile insurance policies in New York.

B. Defendants

12. 21st Century is a New York corporation with its principal place of business in Corona, New York, and is therefore a citizen of New York. 21st Century was incorporated on or about December 19, 2012. The purported owner of 21st Century, Albert Alishayev, is a registered nurse. He is neither a pharmacist nor a physician. According to 21st Century's website, 21st Century promotes itself as "specializ[ing] in no fault and workers' compensation" and represents that it "make[s] it easier for patients to pay for their pharmacy needs by offering Worker's Compensation and No-Fault Insurance." 21st Century assures patients that "if an accident happens, you will be treated and all prescriptions given by the physician will be presented to your insurance carrier who will cover the charges and leave you with no obligations at all."

13. Albert Alishayev resides in and is a citizen of New York. Alishayev is the sole owner of 21st Century. He is a registered nurse, and is neither a physician nor a pharmacist. In addition to owning 21st Century, Alishayev also likely owns and/or controls Express Billing & Collection, Inc. ("Express Billing"). While Istam Itskhakov is listed as Express Billing's incorporator, Alishayev is the registered domain owner of the internet addresses for Express Billing and Alishayev has testified that his wife owns Express Billing. According to its website, Express Billing offers billing, collection, litigation, and arbitration services to healthcare

providers, including assisting providers in navigating independent medical examinations, independent peer reviews, and examinations under oath. Express Billing & Collection purports to “have devised a no fault collection system that spans from the time the documentation is put in place, the billing is filed with the insurance company and all the way to the reimbursement of the medical services rendered.” Alishayev has testified that 21st Century uses Express Billing for its billings. Alishayev also is the registered domain owner of the internet address for Anturio Marketing, Inc. (“Anturio Marketing”). Alishayev has testified that Anturio Marketing “used to do marketing for him.” According to its website, Anturio Marketing “provides referral[] services for individual[s] who have been involved in a car collision.” Anturio Marketing refers auto accident victims to a “suitable medical team or physical therapists,” and then refers them to “Legal Representation . . . to sort out the legalities” which “could involve damage to property/vehicle, insurance claims, personal injury and other issues” that it claims its “lawyers are surely capable of handling.” The chief executive of Anturio Marketing is Peter Khaim. *See* Ex. 2.

14. Timothy Morley resides in and is a citizen of Ohio. Morley is licensed to and practices medicine in New York.

15. Jo-Ann Shakarjian resides in and is a citizen of New Jersey. Shakarjian is licensed to practice medicine in New York and New Jersey and practices medicine in New York.

16. Azu Ajudua resides in and is a citizen of New York. Ajudua is licensed to and practices medicine in New York.

17. Vincentiu Popa resides in and is a citizen of New Jersey. Popa is licensed to and practices medicine in New York and New Jersey.

IV. ALLEGATIONS COMMON TO ALL COUNTS

A. New York's Relevant No-Fault, Pharmaceutical, And Licensure Laws

18. Under New York's No-Fault Comprehensive Motor Vehicle Insurance Reparations Act (N.Y. Ins. Law §§ 5101–06) and related regulations (11 N.Y.C.R.R. §§ 65-1–5) (collectively the “New York No-Fault Laws”), automobile insurers like State Farm Mutual provide mandatory benefits (“No-Fault Benefits”) to their insureds.

19. Mandatory No-Fault Benefits in New York include up to \$50,000 per insured for expenses incurred for medically necessary goods and services following an automobile accident, including medically necessary prescription drugs.

20. The pricing for Compounded Products is dictated by 12 N.Y.C.R.R. § 440.5(a) and (d). First, a provider must determine the national drug code (“NDC”) for each ingredient in the compound. The NDC refers to a unique 10-digit code assigned to each drug that reflects the vendor of the drug, identifies the drug, and indicates the quantity in which the drug is packaged. Each NDC number has a corresponding Average Wholesale Price (“AWP”) in the Red Book published by Thomson Reuters or Medi-Span Master Drug Database by Wolters Kluwer Health, or any successor publisher, on the day a drug is dispensed. *See* 12 N.Y.C.R.R. § 440.2(a).

21. The pricing for Compounded Products is determined at the ingredient level. *See* 12 N.Y.C.R.R. § 440.5(a), (d). To calculate the price of an ingredient, a provider must subtract either 12% if the ingredient is a name brand or 20% if the ingredient is a generic from the AWP and multiply the result by the amount of the ingredient in the compound. To calculate the price of a Compounded Product, the provider adds the cost of the ingredients together and adds a “dispensing fee” of either \$4.00 if the drug is a name brand or \$5.00 if the drug is generic.

22. In addition, the NDC and AWP vary based on the quantity of the drug purchased and/or the supplier. For example, suppliers may provide Diclofenac Na in three (3) different

quantities. Each quantity has its own unique NDC number, which corresponds to a unique AWP. A supplier may provide 25 grams of Diclofenac Na for \$2.60 per gram, 100 grams for \$2.20 per gram, and 500 grams for \$1.84 per gram. Charges must reflect the NDC number and AWP that correspond to the amount of the drug it ordered. If, for example, a provider purchased 500 grams of Diclofenac Na from that supplier for \$1.84 per gram but used the NDC and AWP that corresponded to the purchase of 25 grams of Diclofenac Na for \$2.60 per gram, this would result in overcharging for the resulting Compounded Product.

23. New York law generally requires that “[a]ll prescriptions written in [New York] [for pharmaceutical drugs] shall be issued on an official New York State prescription form provided by the” Department of Health. 10 N.Y.C.R.R. § 910.2(a). The “[o]fficial New York State prescription forms shall be imprinted only with the primary address and other addresses listed on the registration of the facility or practitioner.” 10 N.Y.C.R.R. § 910.4(a)(2).

24. Under New York law, it is unlawful for a physician to directly or indirectly offer, give, solicit, receive, or agree to receive any fee or other consideration to or from a third party for the referral of a patient or in connection with the performance of professional services. *See* N.Y. Educ. Law § 6530(18).

25. Under New York Public Health Law § 238-a, a practitioner authorized to order pharmacy services may not make a referral for such services to a healthcare provider authorized to provide such services, including to compounding pharmacies like 21st Century, where such practitioner has a financial relationship with such healthcare provider. *See also* 10 N.Y.C.R.R. § 34-1.3; N.Y. Pub. Health Law § 238(6) (“‘Health care provider’ shall mean a practitioner in an individual practice, group practice, partnership, professional corporation or other authorized form of association, . . . and any other purveyor of health or health related items or services

including but not limited to a clinical laboratory, a physiological laboratory, a pharmacy, . . . a purveyor of health or health related supplies, appliances or equipment”). A financial relationship includes a compensation arrangement and includes an arrangement with a healthcare provider which is in excess of fair market value or which provides compensation that varies directly or indirectly based on the volume or value of any referrals or business between the parties. *See* N.Y. Pub. Health Law §§ 238(3) and 238-d.

26. Under New York law, it is unlawful for a physician to make a referral to a health care provider, like 21st Century, where the physician has a compensation arrangement with the health care provider which either exceeds fair market value or which provides compensation that varies based directly or indirectly on the value of referrals, without disclosing the relationship to the patient. *See* N.Y. Pub. Health Law § 238-d(1)(b). Any disclosure must not only reveal to the patient the existence of the financial relationship, but must also inform the patient of her right to use a “specifically identified alternative” health care provider. *See* N.Y. Pub. Health Law § 238-d(2). Any violation of Public Health Law § 238(d) by physicians also constitutes professional misconduct under N.Y. Educ. Law § 6530(48).

27. Under New York law, it is unlawful for a physician or chiropractor to exercise undue influence on a patient, including the promotion or the sale of goods or services in such a manner as to exploit the patient for the financial gain of the physician or of a third party, like 21st Century. *See* N.Y. Educ. Law § 6530(17).

28. Consistent with the above-described provisions of New York law prohibiting unlawful referrals, Opinion 8.06 of the American Medical Association Code of Medical Ethics (the “AMA Ethics Code”) provides that: (a) “Physicians should not urge patients to fill prescriptions from an establishment which has entered into a business or other preferential

arrangement with the physician”; (b) “In all instances, physicians should respect the patient’s freedom of choice in selecting who will fill their prescriptions”; (c) patients “have the right to have a prescription filled wherever they wish”; (d) “[P]hysicians should not be influenced in the prescribing of drugs . . . or other treatment by a direct or indirect financial interest in a firm or other supplier, regardless of whether the firm is a manufacturer, distributor, wholesaler, or repackager of the products involved”; and (e) “Physicians should prescribe drugs . . . based solely upon medical considerations and patient need and reasonable expectations of the effectiveness of the drug”

29. Similarly, the Policy Guidelines established by the New York Medicaid Fee Schedule for providers of durable medical equipment (“DME”) and orthotic devices provides that “[t]he choice of which provider will fill the prescription or order for DME. . . or orthotic [devices] rests with the beneficiary.”

30. Consistent with the above-described provisions of New York law prohibiting unlawful financial arrangements to induce referrals and steering patients to a particular provider for health care goods and services, Opinion 8.03 of the AMA’s Ethics Code provides that: “Under no circumstances may physicians place their own financial interests above the welfare of their patients For a physician to unnecessarily . . . prescribe a . . . drug . . . for the physician’s financial benefit is unethical.”

31. Under New York law, a provider of healthcare goods or services is not entitled to No-Fault Benefits if the provider fails to meet any applicable New York state or local licensing requirement necessary to perform such service in New York. *See* 11 N.Y.C.R.R. § 65-3.16(a)(12). Therefore, if 21st Century has financial arrangements with the Prescribing Doctors who are prescribing its medically unnecessary topical Compounded Products to State

Farm Insureds in New York and those arrangements violate N.Y. Education Law § 6530(18) or N.Y. Public Health Law §§ 238(a) and 238-d, 21st Century would be ineligible to collect No-Fault Benefits.

B. Compounded Products And Topical Medications

32. Compounding is a practice in which a licensed pharmacist or physician combines, mixes, or alters individual ingredients into a usable drug product (*i.e.*, Compounded Product) to create a medication tailored to the needs of an individual patient. Compounded Products may be appropriate when the needs of a patient cannot be met by an FDA approved medication. For example, a patient who is allergic to a dye in an FDA approved medication might be provided with a form of the drug without the dye, or an elderly patient or a child who cannot swallow a tablet or capsule might obtain a medicine in a liquid form that is not otherwise available.

33. Compounded drugs generally are not FDA approved, though they may include FDA approved drugs, and generally are exempt from FDA approval. Under federal law, compounding is permitted by a pharmacy like 21st Century if the drug is compounded for an identified individual patient based on the receipt of a valid prescription or a notation, approved by the prescribing practitioner on the prescription order, that a compounded product is necessary for the identified patient. *See* 21 U.S.C. § 353a.

34. When Congress adopted this provision of the Federal Food, Drug and Cosmetic Act governing compounding, 21 U.S.C. § 353a, its express intent was to “ensure continued availability of compounded drug products as a component of individualized therapy, while limiting the scope of compounding so as to prevent manufacturing [of drugs that would otherwise require FDA approval] under the guise of compounding.” H.R. Rep. No. 105-399, at 94 (1997) (Conf. Rep.). As Congress stated at the time, the “exemptions in [the section] are limited to compounding for an individual patient based on the medical need of such patient for

the particular drug compound. To qualify for the exemptions, the pharmacist or physician must be able to cite to a legitimate medical need for the compounded product that would explain why a commercially available drug product would not be appropriate. Medical need would not include compounding drugs that are essentially copies of commercially available drug products for largely economic reasons.” S. Rep. No. 105-43, at 67–68 (1997).

C. 21st Century’s Compounded Products Are Not Medically Necessary For The Conditions For Which They Are Prescribed

35. 21st Century purports to provide to State Farm Insureds Compounded Products in topical creams to treat musculoskeletal pain and neuropathies. *See* Exs. 3–5. 21st Century and the Prescribing Doctors know that 21st Century’s Compounded Products cannot be medically necessary for a number of separate and independent reasons.

1. There Is No Evidence That Certain Of The Drugs In 21st Century’s Compounded Products Applied Topically Can Have A Therapeutic Effect For Musculoskeletal Pain Or Neuropathy

36. First, for certain of the drugs in 21st Century’s Compounded Products, there is no support that they can provide therapeutic benefits in topical form for the conditions for which they are prescribed—musculoskeletal pain and neuropathy.

37. Among the drugs included in 21st Century’s Compounded Products for which there is no evidence in any peer-reviewed literature for a therapeutic effect for musculoskeletal pain or neuropathy in topical form are: Ketorolac, Mometasone, Verapamil HCl, Tranilast, and Levocetirizine. *See* Ex. 1. There are no published, peer-reviewed studies involving patients who suffer from musculoskeletal pain or neuropathy in which topically administered creams containing any of these substances were applied to normal living skin tissue and a therapeutic effect was achieved.

2. There Is No Evidence That The Combinations Of Drugs In 21st Century's Compounded Products Are Effective In Treating Musculoskeletal Pain Or Neuropathy, Are Compatible Or Are Stable

38. Even if there were support for the efficacy of some ingredients used by 21st Century, there would be no legitimate basis for the combination of drugs 21st Century includes in each of its Compounded Products as there is no indication that such combinations are effective in treating the conditions for which they are prescribed, contain drugs that are compatible with each other or are stable over time.

39. 21st Century creates and provides to State Farm Insureds Compounded Products that include as many as nine different purportedly active ingredients and charges as much as almost \$9,000 for typically a 300 gram (or 10 ounces) tube. 21st Century's combination of drugs in its Compounded Products makes no sense clinically, and serves to increase the amount it can charge.

40. Alishayev has admitted that 21st Century performs no independent research on its Compounded Products or conducts any testing or analysis on its Compounded Products.

41. First, there are no published, peer-reviewed studies in which the particular Compounded Products 21st Century provides achieve a therapeutic effect for patients who suffer from musculoskeletal pain or neuropathy. Thus, there is no documentation for the efficacy of the combinations of particular drugs in 21st Century's Compounded Products.

42. Second, there is no benefit from combining the various drugs that make up 21st Century's Compounded Products. There is no evidence in any peer-reviewed literature that the efficacy of 21st Century's Compounded Products is enhanced by adding the multiple drugs contained in these creams. Furthermore, some of the drugs in 21st Century's Compounded Products have the same mechanism of action—that is the specific biochemical interaction through which a drug produces its pharmacological effect. There is no documented benefit to

adding drugs to a Compounded Product that have the same mechanism of action, even if one of those drugs may, on its own, have a positive effect. Indeed, even if any of the drugs had a positive effect, it would be impossible to know which drug, or combination of drugs, was responsible for the result. Moreover, as alleged above, certain of 21st Century's Compounded Products contain drugs with no documented therapeutic benefit in topical form for the conditions for which they are prescribed. There is no legitimate reason to include drugs in a Compounded Product that have no documented therapeutic benefit even if one or more of the drugs contained in the Compounded Product do have a documented therapeutic benefit.

43. Third, there is no basis to conclude that the combinations of drugs contained in 21st Century's Compounded Products are compatible with each other. The absence of any published, peer-reviewed studies involving the particular combinations provided by 21st Century means that there are no studies addressing whether the substances are potentially incompatible. Among other things, it cannot be known whether, as a result of the combination of drugs that make up each of 21st Century's Compounded Products, certain drugs are able to penetrate the skin in sufficient quantities to provide any therapeutic effect. Any drug intended to alleviate pain ultimately should reach nerve or tissue receptors responsible for producing or transmitting such pain.

44. Orally administered drugs are often prescribed for musculoskeletal pain and neuropathies, and they typically reach the relevant receptors by passing from the gastrointestinal system into the bloodstream, and traveling through the bloodstream to the relevant site of action to reduce or alleviate pain. Physicians and other healthcare providers sometimes prescribe topical drugs when they want to avoid gastrointestinal distress or to supply higher peripheral drug concentration. Nevertheless, topical drugs must still reach the relevant peripheral receptors

to have an effect. The relevant peripheral receptors for musculoskeletal pain and neuropathies are in the fascia (fibrous tissue), muscles, tendons, ligaments, and associated nerves. For topically applied drugs to reach these relevant peripheral receptors, they must pass through the barrier layer of the skin (stratum corneum), and into the epidermis, and then typically into the dermis where drugs would then pass into the bloodstream to be distributed to the active receptor sites in the fascia, muscles, tendons, ligaments, and associated nerves.

45. Some of the drugs included in 21st Century's Compounded Products are weak acids,¹ while others are weak bases.² When weak acids and weak bases are combined in the cream base, some portions of each drug may dissolve. These dissolved drug molecules are charged depending on certain qualities of the cream and the drugs. As a result, the dissolved weak acids can be attracted to the dissolved weak bases, forming complexes with unknown properties. Under certain circumstances, it is possible that these weak acid/base complexes will no longer penetrate the outer barrier layer of the skin, so testing on each Compounded Product is necessary to determine whether any complexes form and, if so, what their properties are. It is neither sufficiently documented nor disclosed whether these combinations of drugs interact to produce weak acid/base complexes that cannot penetrate the skin. Absent sufficient confirmation that the combinations in 21st Century's Compounded Products do not create weak acid/base complexes incapable of penetrating the skin, there is simply no reason to combine these drugs in a Compounded Product provided to patients.

¹ Weak acids in the Compounded Products include Diclofenac Na, Baclofen, Ketorolac, Flurbiprofen, Ketoprofen, and Tranilast.

² Weak bases in the Compounded Products include Cyclobenzaprine HCl, Tetracaine HCl, Lidocaine, Clonidine HCl, Tramadol HCl, Bupivacaine HCl, Verapamil HCl, Mometasone, Levocetirizine, Gabapentin, Amantadine HCl, Amitriptyline HCl, Ketamine HCl, Meloxicam, Naproxen, Orphenadrine citrate, Piroxicam, Sumatriptan succinate, and Doxepin HCl.

46. Fourth, 21st Century's Compounded Products are also potentially unstable. Pharmaceutical stability refers to the extent to which a medicine retains its physical and chemical properties and characteristics over time, and is significant because a medicine should have the same properties and characteristics at the time it is used by the patient as it did when it was prepared. Analysis of stability includes testing of products in precisely the combinations at issue, and consideration of peer-reviewed literature on the interactions among the particular drugs at issue, the physical and chemical properties of the individual drugs at issue, the containers in which the products are packaged, likely storage conditions, and expected length of time over which the product will be used.

47. There are no published, peer-reviewed studies addressing whether these substances in combination are stable, safe, or effective. Alishayev has admitted that 21st Century does not conduct any testing or analysis to determine if its Compounded Products are stable, testifying that he "ha[s] no idea" whether the Compounded Products are stable. Absent any indication of whether 21st Century's Compounded Products are stable or for how long they might remain stable, it is impossible to know whether over time they retain the properties and characteristics they held when prepared or whether they physically and chemically degrade rendering them ineffective or potentially even harmful.

48. One ingredient that 21st Century includes in each of its Compounded Products is Versapro, a cream base produced by Medisca that serves as a delivery system for the drugs contained within the Compounded Products and which is charged to State Farm Mutual along with the other ingredients in each Compounded Product. A Compounded Product's base can materially affect the Compounded Product's compatibility, stability, permeability, and efficacy. Yet, 21st Century does not know what effect Versapro has on the compatibility, stability,

permeability, and efficacy of its Compounded Products. Indeed, Alishayev has said that he does not “think it matters what base you use.”

49. 21st Century’s claims list each drug included in its Compounded Products and its base and calculate charges for each separately. As there is no known medical benefit from the combinations of drugs in 21st Century’s Compounded Products, combining the drugs in 21st Century’s Compounded Products serves to increase the charges for the medically unnecessary Compounded Products without any appreciable benefit.

3. There Is No Basis To Believe That 21st Century’s Compounded Products Could Be Medically Necessary Given The Lack Of Evidence Supporting Their Benefit And The Availability Of Many Other Far Less Expensive, FDA Approved, And Proven Alternatives

50. Additionally, 21st Century’s Compounded Products are unnecessary because there is no reason to provide an expensive Compounded Product, whose efficacy is undocumented and unsupported, when there are other widely accepted and effective alternatives with well documented therapeutic benefits at considerably lower cost. Most of the drugs contained in 21st Century’s Compounded Products are available (a) in oral formulations; (b) commercially in different topical formulations; or (c) from similar and related classes of drugs. Some of these alternatives are widely used among practitioners treating these conditions and are FDA approved.

51. Multiple appropriate treatment options exist for common musculoskeletal pains after a motor vehicle accident, including (a) oral non-steroidal anti-inflammatory drugs (NSAIDS) such as the generic Naproxen Sodium 440 mg twice daily for \$4.80 per month or nabumetone (Relafen) 500 mg twice daily for \$35.05 per month; (b) oral NSAIDS that are known to reduce undesirable gastrointestinal side effects such as celecoxib (Celebrex), 100 mg twice daily for \$60.35 per month or meloxicam (Mobic) 15 mg once daily for \$146.25 per

month; (c) oral medications to address pain thru muscle relaxation such as baclofen (Lioresal) 20 mg three times daily for \$96.29 per month, and cyclobenzaprine (Flexeril) 5 mg three times daily for \$45.85 per month which is FDA approved for the treatment of “muscle spasm associated with acute, painful musculoskeletal conditions”; (d) mood stabilization drugs that improve pain such as duloxetine (Cymbalta) 60 mg per day for \$57.60 per month which is FDA approved to treat chronic musculoskeletal pain; (e) oral nerve membrane-stabilizing medications such as gabapentin (Neurontin) up to 900 mg per day for \$10.99 per month; (f) non-compounded topical prescription medications including topical NSAIDS such as diclofenac gel (Voltaren) for \$155.76 per month, and topical anesthetics such as lidocaine available as an over the counter topical gel for about \$40 for a 60 gram tube; and (g) non-compounded over-the-counter topical medications used to treat pain including capsaicin (0.025 to 0.075% concentration, available in a topical patch, cream or gel) that can be applied up to three times daily for \$49.75 per month, and topical anesthetics such as benzocaine (20% concentration, available in a topical spray, cream or gel) that can be applied up to four times daily for \$138.50 per month.

4. 21st Century’s Compounded Products Were Not Tailored To The Unique Needs Of Any Patient And The Purported Prescriptions And Statements Of Medical Necessity Signed By Prescribing Doctors Were Created By 21st Century With Boilerplate Language Designed To Falsely Support The Medical Necessity Of The Compounded Products To Address Unique Patient Needs

(i) Compounded Products Were Not Tailored To Patients

52. Compounded Products must be formulated for individual patients based upon the receipt of a valid prescription for an identified individual patient or a notation on a prescription that a compounded product is necessary for the identified patient. *See* 21 U.S.C. § 353a. The Compounded Products provided by 21st Century were not, however, tailored to or necessary to accommodate unique patient needs. Rather, as reflected in Exhibit 1, a large number of patients

received a relatively small number of formulations. Many patients were provided with identical Compounded Products, and the majority of patients were provided with a small variety of Compounded Products.

53. Prescriptions for 21st Century Compounded Products, rather than reflecting an individualized formulation to accommodate a “unique” patient, simply listed a limited number of predetermined Compounded Products the physician could check or circle. *Id.* The forms even identified the common conditions for which a compound was appropriate. *Id.* For example, forms designated certain Compounded Products as “General Pain Lotions,” appropriate for musculoskeletal pain, tendinitis, strictures, arthritis, and scar therapy, while other Compounded Products were considered appropriate for “Neuropathic and Other Conditions,” including “Neuralgia, Post Herpetic Neuralgia, Shingles, Diabetic Chemo Induced.” *See* Exs. 3–5.

54. While there were three commonly used forms, they differed essentially only in format as the compounded formulations from which physicians could choose on each of the forms were nearly identical. *Compare* Ex. 3 *with* Ex. 4 and Ex. 5. Some forms even include two pre-printed quantities, from which the prescriber could select either “300 ML (4 weeks)” or “150 ML (2 weeks),” thereby directing the prescribers’ choice regarding dosage. The designations themselves are peculiar as the Compounded Products 21st Century purports to provide are measured in grams, a measurement of mass, not milliliters, a measurement of volume. In almost every instance, the Prescribing Doctors circle “300 ML” and 300 grams (or about 10 ounces) are provided. None of the prescriptions for the Compounded Products identifies why a compound was necessary or why a commercially available FDA approved drug would not be appropriate or reference any patient condition that necessitates the prescribed drug, let alone a compound of any kind. Thus, 21st Century’s Compounded Products were not the product of a prescription

necessary to address the unique needs of any individual patient but rather were provided across many patients by different physicians without regard to the particular circumstances of any one patient.

55. If 21st Century's Compounded Products were not compounded for individual patients then, among other things, they required FDA approval as new drugs. *See* 21 U.S.C. § 355 and 21 U.S.C. 353a(a). But 21st Century's Compounded Products are not approved by the FDA. By manufacturing and distributing its mass produced drugs under the guise of purported compounds exempt from FDA approval, 21st Century deliberately sought to avoid the FDA approval regime intended to protect the health and safety of patients.

(ii) Prescriptions For 21st Century's Compounded Products Were Created By 21st Century And Provided To Prescribing Doctors.

56. Alishayev has testified that the Prescribing Doctors prescribed 21st Century's Compounded Products using forms provided directly by 21st Century that contained lists of preprinted Compounded Product formulations.

57. Many of the prescriptions written by the Prescribing Doctors for 21st Century's Compounded Products were written on one of three prescription forms. None of those three forms had the primary address of the Prescribing Doctor who prescribed the Compounded Product or his or her facility. Rather, the only identifying information on the forms, and prominently printed at the top of each of these forms, was identifying information for 21st Century. All three forms included the preprinted email address of 21st Century—general@21centurypharmacy.com—and the fax number for 21st Century. *See* Exs. 3–5. One of the forms provides 21st Century's phone number, address, and has the heading "21st CENTURY PHARMACY." *See* Ex. 5. On the prescription forms, there is a box designated "Prescriber Authorization," which provides blanks to write in, among other things, the physician's name and

contact information, *see* Exs. 3–5, and on two of the forms there is a directive for the physician to indicate whether the pharmacy should “[s]end refills automatically every 30 days.” *See* Exs. 4–5.

58. By providing these form prescriptions to the Prescribing Doctors, 21st Century was orchestrating the delivery of a limited number of mass produced Compounded Products that were not uniquely tailored to the individual needs of any particular patient. The Prescribing Doctors’ use of these prescription forms to prescribe 21st Century’s Compounded Products at different locations to different patients demonstrates that 21st Century’s Compounded Products were not prescribed to address the unique needs of any individual patient.

59. Form prescriptions issued for 21st Century’s Compounded Products violate provisions of New York law whose purpose is clearly to prevent the kinds of practices these prescriptions represent. The listing of multiple predetermined Compounded Products from which physicians can select violates New York Education Law § 6810(7)(a). *See* N.Y. Educ. Law § 6810(7)(a) (“No prescription for a drug written in this state by a person authorized to issue such prescription shall be on a prescription form which authorizes the dispensing or compounding of any other drug. No drug shall be dispensed by a pharmacist when such prescription form includes any other drug.”).

60. Furthermore, the use of blank forms in which a physician’s name is handwritten violates New York Education Law § 6810(8). *See* N.Y. Educ. Law § 6810(8) (“Every prescription (whether or not for a controlled substance) written in this state by a person authorized to issue such prescription and containing the prescriber’s signature shall, in addition to such signature, be imprinted or stamped legibly and conspicuously with the printed name of

the prescriber who has signed the prescription.”); *see also Izzo v. Manhattan Med. Grp., PC*, 164 A.D.2d 13, 560 N.Y.S.2d 644 (1990).

61. In addition, none of the form prescriptions contains the following language required on every prescription in New York: “THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES ‘d a w’ IN THE BOX BELOW.” N.Y. Educ. Law § 6810(6)(a). Thus, form prescriptions violate provisions whose purposes certainly include preventing pharmacies from providing physicians with blank forms containing a predetermined list of medications and limited options in an effort to direct physicians’ decisions, limit patients’ choices, and hinder effective care.

62. Some prescriptions written by the Prescribing Doctors for 21st Century’s Compounded Products were on what appear to be official New York prescription forms. *See Ex. 6*. However, the prescriptions for 21st Century’s Compounded Products on these forms almost always were stamped, rather than written. For example, both Morley and Ajudua, practicing in two different locations, used the same prescription stamp to prescribe the same 21st Century Compounded Products for different patients: “ANTIINFLAMMATORY NEUROPHATIC [*sic*] PAIN CREAM FBGCL CREAM (240 G) FLUBIPROFEN [*sic*] 20% BACLOFEN 2% CYCLOBENZAPRINE 2% GABAPENTIN 10% LIDOCAINE 5% VERSAPRO BASE CREAM 59% SIG: APPLY TO AFFECTED AREA 3 TO 4 TIMES DAILY.” *See Ex. 6*. If 21st Century was the source of the prescription stamps used by the Prescribing Doctors, which it likely was, then 21st Century was orchestrating the delivery of a limited number of Compounded Products in these instances as well. Moreover, the Prescribing Doctors’ use of these stamps to prescribe 21st Century’s Compounded Products at different locations to different patients

demonstrates that the Compounded Products were not prescribed to address the unique needs of any individual patient.

(iii) 21st Century's Boilerplate Letters of Medical Necessity

63. In addition to form prescriptions and stamps, 21st Century purports to support its claims with form letters of medical necessity which the Prescribing Doctors sometimes complete and sign. *See* Ex. 7.

64. The letter of medical necessity generally used by 21st Century to support its claims is a boilerplate form that provides spaces to mark any side effects the patient has had from commercially available oral medications. Ex. 7. The Prescribing Doctors almost never indicate the patient experienced any of the potential side effects from commercially available products. *See, e.g., id.* The letter of medical necessity also includes a section for the physician to indicate why he or she “is prescribing a specially compounded medication” by marking a predetermined list of reasons. The Prescribing Doctors invariably mark at least one of these reasons (and sometimes all of them), *see, e.g., id.*, despite almost never providing any support for those reasons. In several instances, the Prescribing Doctors indicate on the letter of medical necessity that “[t]he patient is intolerant of commercially available products” even though no “side effects from commercially available oral medications” included on the form have been checked. None of these letters substantiates any of the reasons given for why a Compounded Product was prescribed.

65. Compounded Products should only be prescribed when other FDA approved medication cannot meet the needs of an individual patient and when they are tailored to the unique needs of a particular patient. The Prescribing Doctors were responsible for the vast majority of prescriptions for 21st Century's Compounded Products in New York. State Farm

Mutual is aware of fewer than approximately 10 physicians that actually wrote the majority of prescriptions for 21st Century Compounded Products in New York

66. Although the Prescribing Doctors mostly operate out of different locations, they use essentially the same commonly used form prescriptions. Several of the Prescribing Doctors signed the form letters of medical necessity purporting to identify various generic, preprinted reasons for why the Compounded Products were purportedly necessary with little to no support for those reasons. *See, e.g., id.* That so few doctors prescribed such a high proportion of 21st Century's Compounded Products and that the patterns in the prescriptions and documentation of the Prescribing Doctors are so consistent and not credible further establishes that 21st Century's Compounded Products were not created or prescribed for the individual needs of a particular patient and were not medically necessary.

5. 21st Century And The Prescribing Doctors Take Steps To Ensure That Patients Obtain The Compounded Products From 21st Century

67. In addition to furnishing the Prescribing Doctors with form prescriptions and, likely, letters of medical necessity, 21st Century, along with the Prescribing Doctors, ensured that patients would obtain the exorbitant Compounded Products from 21st Century.

68. Alishayev employs consultants who market 21st Century's services to healthcare providers and are used to ensure 21st Century fills patient prescriptions. These consultants provide blank 21st Century prescription forms to Prescribing Doctors and then collect them after they have been completed and signed. The consultants return the completed prescription forms to 21st Century which fills the prescriptions, delivers the Compounded Products to patients, and then bills State Farm Mutual. One of the Prescribing Doctors, Dr. Noel Howell, testified that a 21st Century representative comes to his office once every week or two weeks to pick up the prescriptions for 21st Century's Compounded Products. Dr. Howell acknowledged that when he

prescribes medications other than 21st Century's Compounded Products and patches, he gives the prescriptions to the patient for the patient to take to the pharmacy of his or her choice.

69. Patients have testified that, instead of being given prescriptions for the Compounded Products by the Prescribing Doctors to fill at a pharmacy of their choice, they receive the Compounded Products either at the Prescribing Doctor's office or by mail. A patient of Dr. Ajudua's testified that his prescription for a Compounded Product was given to "[t]he ladies at the front desk" and that he received the Compounded Product thereafter through the mail. This conduct is intended by 21st Century and the Prescribing Doctors to ensure that patients obtain Compounded Products only from 21st Century. The same or similar Compounded Products could be obtained from many other suppliers and there is therefore no legitimate reason why prescriptions should be directed to 21st Century. If there is a financial arrangement between 21st Century and the Prescribing Doctors, directing patients to obtain Compounded Products exclusively from 21st Century violates Public Health Law § 238(d)(1) and (2), which require the Prescribing Doctors to disclose their financial arrangements and provide patients with a specific alternative provider other than 21st Century.

D. 21st Century's Submissions To State Farm Mutual

70. 21st Century purports to provide the Compounded Products directly to patients and submits bills and supporting documentation to State Farm Mutual in which it represents that the Compounded Products are medically necessary and entitled to reimbursement. The claims, which list ingredients by item and charge separately for each, are for as much as almost \$9,000 per tube of cream. In fact, 21st Century knew that the Compounded Products were medically unnecessary and were not entitled to reimbursement.

71. 21st Century's charges are typically supported by a Health Insurance Claim Form (known as a "CMS-1500"), a Verification of Treatment by Attending Physician or Other

Provider of Health Service (“Verification”), and an Attached Services sheet, and/or a Statement of Account, delivery slip or other summary of the items purportedly provided to patients, each of which, among other things, lists the purported active ingredients in the Compounded Products, the quantity of each such ingredient, and the price for each such ingredient. State Farm Mutual also receives prescriptions from the Prescribing Doctors and other providers and letters of medical necessity signed by the Prescribing Doctors.

72. 21st Century’s submissions include NDC numbers which identify the ingredients in the Compounded Products and their source, and represent that 21st Century obtains virtually all of its ingredients for Compounded Products provided to State Farm Insureds from a single source, Medisca.

73. Charges submitted by a provider should reflect the proper NDC number and AWP for the drugs included in the compound as well as the quantity in which the drugs were obtained by the provider. From 21st Century’s submissions, it is impossible to determine whether it actually obtained its ingredients in the quantities it represents through the NDC numbers and AWP’s it uses or whether it obtained those drugs in larger quantities. If it obtained drugs in larger quantity at discounted prices, but submitted claims using NDC numbers and AWP’s representing that it had obtained drugs in smaller quantities at higher prices, its representations would be fraudulent.

74. In any event, 21st Century charges exorbitant amounts for its Compounded Products often without regard to the applicable fee schedule. In New York, for each drug in its Compounded Products, 21st Century should charge no more than AWP minus 12% for each brand name drug and no more than AWP minus 20% for each generic drug. Yet, 21st Century’s

New York charges are almost always based on the AWP without any reduction of either 12% or 20%.

75. 21st Century's prices are based on the AWP for Medisca listed in the Red Book. But these reported AWP's are many times the prices at which Medisca lists its drugs for sale to purchasers on Medisca's ordering system. As a result, 21st Century's prices represent extraordinary markups over what 21st Century is likely paying its purported supplier, Medisca, for its ingredients. For example, using Medisca's reported AWP, 21st Century charges approximately \$59.85 per gram for Gabapentin. But Medisca sells 100 grams of Gabapentin for \$159 or \$1.59 per gram, meaning that 21st Century's charges are almost 37 times what it likely pays Medisca for Gabapentin. Similarly, using Medisca's reported AWP, 21st Century charges approximately \$3.20 per gram from Versapro cream base. But Medisca sells 5 kilograms of Versapro cream base for \$369 or \$0.0738 per gram, meaning that 21st Century charges more than 43 times what it likely pays Medisca for Versapro cream base. These enormous markups give 21st Century every incentive to provide medically unnecessary Compounded Products and to combine additional drugs, each of which is charged separately, in each Compounded Product. Moreover, the Prescribing Doctors know the exorbitant cost of 21st Century's Compounded Products. For example, when one of the Prescribing Doctors, Noel Howell, was asked if he knew how expensive 21st Century's Compounded Products are, he responded that he could "lie and say, I don't know, . . . but I have seen a bill, yes"

76. Given the lack of evidence supporting the therapeutic benefits of 21st Century's Compounded Products, the availability of many commercially available, far less expensive, FDA approved oral and topical medications that are proven to be therapeutic for musculoskeletal pain

and neuropathies, and the exorbitant charges that 21st Century attempts to collect, there is no legitimate reason for the Prescribing Doctors to prescribe 21st Century's Compounded Products.

77. To the extent the Prescribing Doctors prescribe 21st Century's Compounded Products pursuant to financial or other arrangements with 21st Century that would violate applicable licensing laws, 21st Century would not be eligible to collect No-Fault Benefits in New York, and it would be inequitable and contrary to the public policy of New York to allow 21st Century or the Prescribing Doctors to retain any benefits obtained from such arrangements. *See* 11 N.Y.C.R.R. § 65-3.16(a)(12).

E. State Farm Mutual's Justifiable Reliance

78. 21st Century, Alishayev, and the Prescribing Doctors are obligated legally and ethically to act honestly and with integrity. Yet, 21st Century, Alishayev, and the Prescribing Doctors submitted, or caused to be submitted, bills and supporting documentation that are fraudulent in that they represent that the Compounded Products were medically necessary when, in fact, they were not.

79. State Farm Mutual is under statutory and contractual obligations to pay No-Fault Benefits promptly for medically necessary services that are lawfully rendered. The bills and supporting documents that 21st Century, Alishayev, and the Prescribing Doctors submitted and/or caused to be submitted to State Farm Mutual in support of the fraudulent charges at issue, combined with the material misrepresentations described above, were designed to and did cause State Farm Mutual to justifiably rely on them.

80. As a result, State Farm Mutual has incurred damages of more than \$1.6 million in benefits paid based upon the fraudulent charges.

81. Based upon 21st Century, Alishayev, and the Prescribing Doctors' material misrepresentations and other affirmative acts to conceal its fraud from State Farm Mutual, State

Farm Mutual did not discover and could not have reasonably discovered that its damages were attributable to fraud until shortly before it filed this Complaint. Each bill and its supporting documentation, when viewed in isolation, does not reveal its fraudulent nature. Only when the bills and supporting documentation are viewed together as a whole do the patterns emerge revealing the fraudulent nature of all the bills and supporting documentation.

V. CAUSES OF ACTION

**FIRST CLAIM FOR RELIEF
COMMON LAW FRAUD**

(Against 21st Century and Alishayev)

82. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

83. 21st Century and Alishayev intentionally and knowingly made false and fraudulent statements of material fact to State Farm Mutual by submitting, and causing to be submitted, bills and supporting documentation that contained false and fraudulent representations of material fact.

84. The false and fraudulent representations of material fact include the representations in each and every claim described in the charts attached hereto as Ex.1 that the Compounded Products prescribed and provided were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

85. Specifically, 21st Century and Alishayev provided the Compounded Products prescribed by the Prescribing Doctors to patients and then submitted fraudulent bills and supporting documentation, including the prescriptions and letters of medical necessity signed by the Prescribing Doctors, to State Farm Mutual.

86. 21st Century and Alishayev knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made.

87. 21st Century, under Alishayev's direction, made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely on such misrepresentations.

88. As a result of State Farm Mutual's justifiable reliance on these misrepresentations, State Farm Mutual has incurred damages of more than \$1.6 million.

WHEREFORE, State Farm Mutual demands judgment against Defendant 21st Century and Alishayev for compensatory damages, costs, and other such relief as this Court deems equitable, just, and proper.

**SECOND CLAIM FOR RELIEF
UNJUST ENRICHMENT**

(Against 21st Century and Alishayev)

89. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

90. State Farm Mutual conferred a benefit upon 21st Century and Alishayev by paying 21st Century's claims for Compounded Products purportedly provided to patients and 21st Century and Alishayev voluntarily accepted and retained the benefit of those payments.

91. Because 21st Century and Alishayev knowingly submitted, or caused to be submitted, charges for Compounded Products that were not medically necessary and were not reimbursable, the circumstances are such that it would be inequitable to allow it to retain the benefit of the monies paid.

92. As a direct and proximate result of the above-described conduct of 21st Century and Alishayev, State Farm Mutual has been damaged and 21st Century and Alishayev have been unjustly enriched by more than \$1.6 million.

WHEREFORE, State Farm Mutual demands judgment against Defendant 21st Century and Alishayev for compensatory damages, plus interest and costs, and for such other relief as this Court deems equitable, just, and proper.

**THIRD CLAIM FOR RELIEF
COMMON LAW FRAUD**

(Against 21st Century, Alishayev, Morley)

93. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

94. 21st Century, Alishayev, and Morley conspired, agreed to, and did act in concert by intentionally and knowingly making, false and fraudulent statements of material fact to State Farm Mutual by submitting, and causing to be submitted, bills and supporting documentation that contained false and fraudulent representations of material fact.

95. The false and fraudulent representations of material fact include the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Morley and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

96. Specifically, Morley wrote prescriptions to patients for 21st Century's Compounded Products and letters of medical necessity purporting to support the necessity of those Compounded Products knowing that those Compounded Products were not medically necessary. 21st Century and Alishayev then provided those Compounded Products to patients

and then submitted fraudulent bills and supporting documentation, including the prescriptions and letters of medical necessity signed by Morley, to State Farm Mutual.

97. 21st Century, Alishayev, and Morley knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made.

98. 21st Century, Alishayev, and Morley made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely upon such misrepresentations.

99. As a result of State Farm Mutual's justifiable reliance on these misrepresentations, State Farm Mutual has incurred damages of more than \$420,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Morley for compensatory damages, costs, and other such relief as this Court deems equitable, just, and proper.

**FOURTH CLAIM FOR RELIEF
AIDING AND ABETTING FRAUD**

(Against 21st Century, Alishayev, and Morley)

100. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

101. 21st Century, Alishayev, and Morley conspired, agreed to, and did act in concert to defraud State Farm Mutual and did defraud State Farm Mutual, through the submission of false and fraudulent statements of material fact to State Farm Mutual concerning Compounded Products.

102. Each of the Defendants substantially assisted in the defrauding of State Farm. Morley wrote prescriptions to patients for 21st Century's Compounded Products and letters of

medical necessity purporting to support the necessity of those Compounded Products knowing that those Compounded Products were not medically necessary.

103. 21st Century and Alishayev submitted, and caused to be submitted, bills and supporting documentation that contained false and fraudulent misrepresentations of material fact, including the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Morley and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

104. The false and fraudulent statements of material fact include the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products provided by 21st Century and Alishayev and prescribed by Morley were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

105. Defendants knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made. Defendants made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely upon such misrepresentations.

106. As a direct and proximate result of the Defendants' fraud, which was aided and abetted by each and every Defendant, State Farm justifiably relied on the Defendants' fraudulent misrepresentations and has incurred damages of more than \$420,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Morley for compensatory damages, plus interest and costs, and for such other relief as the Court deems equitable, just and proper.

**FIFTH CLAIM FOR RELIEF
UNJUST ENRICHMENT**

(Against 21st Century, Alishayev, Morley)

107. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

108. State Farm Mutual conferred a benefit upon 21st Century, Alishayev, and Morley by paying 21st Century's claims for Compounded Products purportedly provided to Morley's patients identified in Exhibit 1, and 21st Century, Alishayev, and Morley voluntarily accepted and retained the benefit of those payments.

109. Because 21st Century, Alishayev, and Morley knowingly submitted, or caused to be submitted, charges for Compounded Products that were not medically necessary and were not reimbursable, the circumstances are such that it would be inequitable to allow it to retain the benefit of the monies paid.

110. As a direct and proximate result of the above-described conduct of 21st Century, Alishayev, and Morley, State Farm Mutual has been damaged and 21st Century, Alishayev, and Morley have been unjustly enriched by more than \$420,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Morley for compensatory damages, plus interest and costs, and for such other relief as this Court deems equitable, just, and proper.

**SIXTH CLAIM FOR RELIEF
COMMON LAW FRAUD**

(Against 21st Century, Alishayev, Ajudua)

111. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

112. 21st Century, Alishayev, and Ajudua conspired, agreed to, and did act in concert by intentionally and knowingly making false and fraudulent statements of material fact to State Farm Mutual by submitting, and causing to be submitted, bills and supporting documentation that contained false and fraudulent representations of material fact.

113. The false and fraudulent representations of material fact include the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Ajudua and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

114. Specifically, Ajudua wrote prescriptions to patients for 21st Century's Compounded Products and letters of medical necessity purporting to support the necessity of those Compounded Products knowing that those Compounded Products were not medically necessary. 21st Century and Alishayev then provided those Compounded Products to patients and then submitted fraudulent bills and supporting documentation, including the prescriptions and letters of medical necessity signed by Ajudua, to State Farm Mutual.

115. 21st Century, Alishayev, and Ajudua knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made.

116. 21st Century, Alishayev, and Ajudua made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely upon such misrepresentations.

117. As a result of State Farm Mutual's justifiable reliance on these misrepresentations, State Farm Mutual has incurred damages of more than \$120,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Ajudua for compensatory damages, costs, and other such relief as this Court deems equitable, just, and proper.

**SEVENTH CLAIM FOR RELIEF
AIDING AND ABETTING FRAUD**

(Against 21st Century, Alishayev, Ajudua)

118. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

119. 21st Century, Alishayev, and Ajudua conspired, agreed to, and did act in concert to defraud State Farm Mutual and did defraud State Farm Mutual, through the submission of false and fraudulent statements of material fact to State Farm Mutual concerning Compounded Products.

120. Each of the Defendants substantially assisted in the defrauding of State Farm Mutual. Ajudua wrote prescriptions to patients for 21st Century's Compounded Products and letters of medical necessity purporting to support the necessity of those Compounded Products knowing that those Compounded Products were not medically necessary.

121. 21st Century and Alishayev submitted, and caused to be submitted, bills and supporting documentation that contained false and fraudulent misrepresentations of material fact, including the representations in each and every claim described in the charts attached hereto as

Ex. 1 that the Compounded Products prescribed by Ajudua and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

122. The false and fraudulent statements of material fact include the representations in each and every claim described in the charts attached hereto as Ex.1 that the Compounded Products provided by 21st Century and Alishayev and prescribed by Ajudua were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

123. Defendants knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made. Defendants made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely upon such misrepresentations.

124. As a direct and proximate result of the Defendants' fraud, which was aided and abetted by each and every Defendant, State Farm Mutual justifiably relied on the Defendants' fraudulent misrepresentations and has incurred damages of more than \$120,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Ajudua for compensatory damages, plus interest and costs, and for such other relief as the Court deems equitable, just and proper.

**EIGHTH CLAIM FOR RELIEF
UNJUST ENRICHMENT**

(Against 21st Century, Alishayev, and Ajudua)

125. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

126. State Farm Mutual conferred a benefit upon 21st Century, Alishayev, and Ajudua by paying 21st Century's claims for Compounded Products purportedly provided to Ajudua's patients identified in Exhibit 1, and 21st Century, Alishayev, and Ajudua voluntarily accepted and retained the benefit of those payments.

127. Because 21st Century, Alishayev, and Ajudua knowingly submitted, or caused to be submitted, charges for Compounded Products that were not medically necessary and were not reimbursable, the circumstances are such that it would be inequitable to allow it to retain the benefit of the monies paid.

128. As a direct and proximate result of the above-described conduct of 21st Century, Alishayev, and Ajudua, State Farm Mutual has been damaged and 21st Century, Alishayev, and Ajudua have been unjustly enriched by more than \$120,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Ajudua for compensatory damages, plus interest and costs, and for such other relief as this Court deems equitable, just, and proper.

**NINTH CLAIM FOR RELIEF
COMMON LAW FRAUD**

(Against 21st Century, Alishayev, Shakarjian)

129. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

130. 21st Century, Alishayev, and Shakarjian conspired, agreed to, and did act in concert by intentionally and knowingly making false and fraudulent statements of material fact to State Farm Mutual by submitting, and causing to be submitted, bills and supporting documentation that contained false and fraudulent representations of material fact.

131. The false and fraudulent representations of material fact include the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Shakarjian and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

132. Specifically, Shakarjian wrote prescriptions to patients for 21st Century's Compounded Products and letters of medical necessity purporting to support the necessity of those Compounded Products knowing that those Compounded Products were not medically necessary. 21st Century and Shakarjian then provided those Compounded Products to patients and then submitted fraudulent bills and supporting documentation, including the prescriptions and letters of medical necessity signed by Shakarjian, to State Farm Mutual.

133. 21st Century, Alishayev, and Shakarjian knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made.

134. 21st Century, Alishayev, and Shakarjian made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely on such misrepresentations.

135. As a result of State Farm Mutual's justifiable reliance on these misrepresentations, State Farm Mutual has incurred damages of more than \$90,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Shakarjian for compensatory damages, costs, and other such relief as this Court deems equitable, just, and proper.

**TENTH CLAIM FOR RELIEF
AIDING AND ABETTING FRAUD**

(Against 21st Century, Alishayev, Shakarjian)

136. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

137. 21st Century, Alishayev, and Shakarjian conspired, agreed to, and did act in concert to defraud State Farm Mutual, and did defraud State Farm Mutual, through the submission of false and fraudulent statements of material fact to State Farm Mutual concerning Compounded Products.

138. Each of the Defendants substantially assisted in the defrauding of State Farm Mutual. Shakarjian wrote prescriptions to patients for 21st Century's Compounded Products and letters of medical necessity purporting to support the necessity of these Compounded Products knowing that those Compounded Products were not medically necessary.

139. 21st Century and Alishayev submitted, and caused to be submitted, bills and supporting documentation that contained false and fraudulent misrepresentations of material fact, including the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Shakarjian and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

140. The false and fraudulent statements of material fact include the representations in each and every claim described in the charts attached hereto as Ex.1 that the Compounded Products provided by 21st Century and Alishayev and prescribed by Shakarjian were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

141. Defendants knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made. Defendants made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely upon such misrepresentations.

142. As a direct and proximate result of the Defendants' fraud, which was aided and abetted by each and every Defendant, State Farm Mutual justifiably relied on the Defendants' fraudulent misrepresentations and has incurred damages of more than \$90,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Shakarjian for compensatory damages, plus interest and costs, and for such other relief as the Court deems equitable, just and proper.

**ELEVENTH CLAIM FOR RELIEF
UNJUST ENRICHMENT**

(Against 21st Century, Alishayev, and Shakarjian)

143. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

144. State Farm Mutual conferred a benefit upon 21st Century, Alishayev, and Shakarjian by paying 21st Century's claims for Compounded Products purportedly provided to Shakarjian's patients identified in Exhibit 1, and 21st Century, Alishayev, and Sharkarjian voluntarily accepted and retained the benefit of those payments.

145. Because 21st Century, Alishayev, and Shakarjian knowingly submitted, or caused to be submitted, charges for Compounded Products that were not medically necessary and were not reimbursable, the circumstances are such that it would be inequitable to allow it to retain the benefit of the monies paid.

146. As a direct and proximate result of the above-described conduct of 21st Century, Alishayev, and Shakarjian, State Farm Mutual has been damaged and 21st Century, Alishayev, and Shakarjian have been unjustly enriched by more than \$90,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Shakarjian for compensatory damages, plus interest and costs, and for such other relief as this Court deems equitable, just, and proper.

**TWELFTH CLAIM FOR RELIEF
COMMON LAW FRAUD**

(Against 21st Century, Alishayev, Popa)

147. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

148. 21st Century, Alishayev, and Popa conspired, agreed to, and did act in concert by intentionally and knowingly making false and fraudulent statements of material fact to State Farm Mutual by submitting, and causing to be submitted, bills and supporting documentation that contained false and fraudulent representations of material fact.

149. The false and fraudulent representations of material fact include the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Popa and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

150. Specifically, Popa wrote prescriptions to patients for 21st Century's Compounded Products and letters of medical necessity purporting to support the necessity of those Compounded Products knowing that those Compounded Products were not medically necessary. 21st Century and Popa then provided those Compounded Products to patients and then submitted

fraudulent bills and supporting documentation, including the prescriptions and letters of medical necessity signed by Popa, to State Farm Mutual.

151. 21st Century, Alishayev, and Popa knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made.

152. 21st Century, Alishayev, and Popa made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely on such misrepresentations.

153. As a result of State Farm Mutual's justifiable reliance on these misrepresentations, State Farm Mutual has incurred damages of more than \$80,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Popa for compensatory damages, costs, and other such relief as this Court deems equitable, just, and proper.

**THIRTEENTH CLAIM FOR RELIEF
AIDING AND ABETTING FRAUD**

(Against 21st Century, Alishayev, Popa)

154. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

155. 21st Century, Alishayev, and Popa conspired, agreed to, and did act in concert to defraud State Farm Mutual, and did defraud State Farm Mutual, through the submission of false and fraudulent statements of material fact to State Farm Mutual concerning Compounded Products.

156. Each of the Defendants substantially assisted in the defrauding of State Farm Mutual. Popa wrote prescriptions to patients for 21st Century's Compounded Products and

letters of medical necessity purporting to support the necessity of these Compounded Products knowing that those Compounded Products were not medically necessary.

157. 21st Century and Alishayev submitted, and caused to be submitted, bills and supporting documentation that contained false and fraudulent misrepresentations of material fact, including the representations in each and every claim described in the charts attached hereto as Ex. 1 that the Compounded Products prescribed by Popa and provided by 21st Century, under the direction of Alishayev, were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

158. The false and fraudulent statements of material fact include the representations in each and every claim described in the charts attached hereto as Ex.1 that the Compounded Products provided by 21st Century and Alishayev and prescribed by Popa were medically necessary and reimbursable when, in fact, they were not medically necessary and not reimbursable.

159. Defendants knew that the above-described misrepresentations made to State Farm Mutual relating to the Compounded Products were false and fraudulent when they were made. Defendants made the above-described misrepresentations and engaged in such conduct to induce State Farm Mutual into relying on the misrepresentations, and State Farm Mutual did, in fact, rely upon such misrepresentations.

160. As a direct and proximate result of the Defendants' fraud, which was aided and abetted by each and every Defendant, State Farm Mutual justifiably relied on the Defendants' fraudulent misrepresentations and has incurred damages of more than \$80,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Popa for compensatory damages, plus interest and costs, and for such other relief as the Court deems equitable, just and proper.

**FOURTEENTH CLAIM FOR RELIEF
UNJUST ENRICHMENT**

(Against 21st Century, Alishayev, and Popa)

161. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

162. State Farm Mutual conferred a benefit upon 21st Century, Alishayev, and Popa by paying 21st Century's claims for Compounded Products purportedly provided to Popa's patients identified in Exhibit 1, and 21st Century, Alishayev, and Popa voluntarily accepted and retained the benefit of those payments.

163. Because 21st Century, Alishayev, and Popa knowingly submitted, or caused to be submitted, charges for Compounded Products that were not medically necessary and were not reimbursable, the circumstances are such that it would be inequitable to allow it to retain the benefit of the monies paid.

164. As a direct and proximate result of the above-described conduct of 21st Century, Alishayev, and Popa, State Farm Mutual has been damaged and 21st Century, Alishayev, and Popa have been unjustly enriched by more than \$80,000.

WHEREFORE, State Farm Mutual demands judgment against Defendants 21st Century, Alishayev, and Popa for compensatory damages, plus interest and costs, and for such other relief as this Court deems equitable, just, and proper.

**FIFTEENTH CLAIM FOR RELIEF
DECLARATORY JUDGMENT**

(Against 21st Century)

165. State Farm Mutual incorporates, adopts, and re-alleges as though fully set forth herein each and every allegation in paragraphs 1 through 81 above.

166. This is an action for declaratory relief pursuant to 28 U.S.C. § 2201.

167. There is an actual case and controversy between State Farm Mutual, on the one hand, and 21st Century, on the other hand, as to all charges for Compounded Products that have not been paid to date and through the trial of this case. State Farm Mutual contends that 21st Century is not entitled to reimbursement for any of these charges.

168. Because 21st Century has made false and fraudulent statements, otherwise engaged in the above-described fraudulent conduct with the intent to conceal and misrepresent material facts and circumstances regarding claims submitted to State Farm Mutual, and otherwise submitted claims and charges that are not entitled to reimbursement, 21st Century is not entitled to any coverage for No-Fault Benefits for the claims and charges at issue.

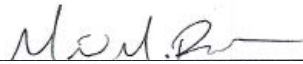
WHEREFORE, State Farm Mutual respectfully requests a judgment declaring that Defendant 21st Century is not entitled to collect No-Fault Benefits for any unpaid charges to date and through the trial of this case, and for supplementary relief, attorneys' fees, interest, and costs as this Court deems equitable, just, and proper.

JURY DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), State Farm Mutual demands a trial by jury.

Dated: October 5, 2017
New York, New York

Respectfully submitted,

By: 
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